

## **REMARKS**

The issues outstanding in the Final Rejection mailed August 7, 2008, are the rejections under 35 U.S.C. §§ 112, 102 and the doctrine of obviousness-type double patenting. Reconsideration of these rejections, in view of the following discussion, is respectfully requested.

### **Rejections under 35 U.S.C. § 112**

Claims 1-4, 6-9 and 11-14 have been rejected under 35 U.S.C. § 112, first paragraph. Reconsideration of this rejection is respectfully requested. It is argued, on page 2 of the Office Action, that the claims reciting “solvates” of the compounds are not enabled. It is believed amply explained in applicants’ prior response that the production of solvates is wholly conventional in the art, and well enabled by the disclosure. Although page 4 of the Office Action notes that the rejection is maintained because, allegedly, applicants have not provided “sufficient data or evidence” showing that the compounds can, indeed, make solvates, the Office Action does not comment on applicants’ prior discussion concerning the conventionality of solvates and, moreover, appears to require a showing that the specific compounds herein can be demonstrated to form solvates. Such is clearly not the standard of enablement under *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971).

However, in order to expedite prosecution, the term “solvates” has been cancelled from the claims. Withdrawal of this rejection is therefore respectfully requested.

Claims 11-13 have been rejected under 35 U.S.C. § 112, first paragraph. It is argued, at page 4 of the Office Action, that although the specification enables the treatment of premenstrual disorders through inhibition of 5-HT and/or selective serotonin reuptake inhibitors, the specification does “not reasonably provide enablement for the treatment” of all disorders associated with these receptors. Applicants respectfully disagree with this analysis.

First, it is noted that, in order to expedite prosecution and focus discussion, claims 11 and 13 have been cancelled. New claim 15 has been added, directed to two of the methods also recited in claim 12, anxiolytic or antidepressant effects.

With respect to claim 12, it appears that the arguments in the Office Action respecting this claim are that a wide variety of methods are recited therein. To the extent that the rejection

is based solely on breath of the claims, such is impermissible under relevant law. For example, *Marzocchi*, *supra*, clearly sets forth the rationale for assessing enablement of a claim. First, the question is whether “objective enablement” has been furnished. Objective enablement is as simple as a statement, of the same scope as the claims, that all compounds encompass therein are usable in the methods as stated. This is clearly present in the current specification. The *Marzocchi* court then indicated that it is incumbent upon the Patent and Trademark Office to provide “reasons or evidence” why the statement of objective enablement would be disputed. The court cautioned that breath, alone, is insufficient to constitute such reasons or enablement. The present Office Action provides absolutely no discussion of, or reasons or evidence why, any of the methods of claim 12 would not be treatable with the compounds as claimed. In fact, by contrast, the present specification provides ample evidence that the compounds as claimed would be usable in the methods, as a result of their activity as serotonin reuptake inhibitors. See, for example, pages 1-2 and pages 11-15 of the present specification, indicating that the claimed compounds exhibit serotonin agonistic and antagonistic properties, and thus are particularly suitable as anti-depressants and anxiolytics. In particular, note the second paragraph at page 13 of the specification.

Moreover, even if the Patent and Trademark Office were to have presented reasons or evidence why the objective enablement in the specification would be doubted, the specification still enables the present compounds inasmuch as it does not require undue experimentation to test a given compound for affinity to the 5-HT receptor, for example, in conventional receptor binding tests as detailed at page 11, line 16 through page 12, line 4, and example 3. Accordingly, withdrawal of the rejection to 35 U.S.C. § 112 is respectfully requested as it pertains to claim 12.

Claim 11 has been rejected under 35 U.S.C. § 112, second paragraph. Cancellation of this claim renders the rejection moot.

Claim 4 has been rejected under 35 U.S.C. § 112, second paragraph. It is argued that it is unclear what “alcohol protecting groups” are referred to in the claim. Indeed, protection of alcohol protecting groups is conventional and would be well understood by one of ordinary skill in the art with even a basic understanding of organic chemistry. The fact that the specification does not spell out specific alcohol protecting groups is in no way dispositive of indefiniteness.

However, in order to expedite prosecution, the term has been cancelled, and withdrawal of the rejection is respectfully requested.

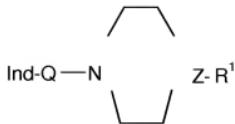
**Double Patenting**

Claims 1, 3, 4, 6 and 14 have been under the Doctrine of obviousness-type double patenting. However, while the statement of the rejection references application serial no. 10/539,516, the detailed discussion of the rejection, on the other hand, references application serial no. 10/481,270. Accordingly, applicants are unable to determine which application is intended in the rejection. A request for clarification and for a new Office Action was mailed on August 27, 2008. That request has gone unanswered. Accordingly, applicants *can not* respond to the double patenting rejection. It is submitted that any subsequent Office Action must provide clarification and a proper statement of the rejection in the form of a new non-final Office Action in order for applicants to respond.

**Rejections under 35 U.S.C. § 102**

Claims 1-4, 6-9 and 11-14 remain rejected under 35 U.S.C. § 102(b) over Bottcher '241, over Bathe '794 and over Bartoszyk '989. Although applicants provided a detailed discussion of these references in their prior reply, noting how the disclosures of the references *do not* disclose any compounds within the present scope, the Office Action maintains the rejection arguing that the "compounds have valid groups form [sic, from] compounds of instant claim 1." On the one hand, this is not an adequate standard for anticipation. See *In re Marshall*, 577 F.2d 301, 198 U.S.P.Q. 344 (CCPA 1978), holding that all material elements of a claim must be disclosed in a reference for that reference to anticipate. While applicants do not fully understand this sentence at the bottom of page 8 of the Office Action, it is submitted that the disclosures of the references do not disclose compounds within the present scope, i.e., do not provide any anticipatory species, and that the present claims do not read on the reference.

In particular, Bottcher discloses compounds of the formula



wherein "Ind" is an "indol-3-yl radical which is unsubstituted or mono or polysubstituted" by various moieties. It is clear from this disclosure, e.g., at column 2, defining "Ind" as an indol-3-yl radical *substituted in the 5-position*, and moreover by the species of the examples, which disclose 5-substituted indoles, that the patent fails to suggest indoles which are substituted *on the nitrogen atom*, i.e., 1-substituted. Note that the presently claimed compounds are substituted in the 1 position (on a nitrogen atom) by R<sup>2</sup>, which is alkyl which may be mono or polysubstituted by halogen, or is alkaryl, alkheteroaryl, or heteroaryl. It is thus clear that the patent fails to anticipate such claims. Withdrawal of the rejection is therefore respectfully requested.

As with Bottcher, Bathe discloses only compounds which are unsubstituted on the nitrogen atom of an indole moiety. Note that the compounds of Bathe are 5-cyano. Accordingly, the publication also fails to anticipate the present claims.

Finally, Bartoszyk also fails to disclose N-substituted indoles. Note that the '989 disclosure is directed to new indications for use of the compounds disclosed in Bottcher '241, at page 3, lines 6-10. Other compounds disclosed similarly lack the above-noted substitution. See page 2, lines 23-28, disclosing 5-cyano indols and 1H indols. Accordingly, this reference also fails to anticipate the present claims. It is submitted that, should these rejections be maintained, it is incumbent upon the office to provide an explanation of where, in each reference, an anticipatory disclosure is to be found, inasmuch as none of the references disclose N-substituted indoles. Withdrawal of the rejection is again respectfully requested.

Finally, the Office Action mentions WO 02/083666 as "prior art" but does not apply the disclosure in a rejection. Thus, no comment thereon is deemed necessary.

The claims of the application are submitted to be in condition for allowance, however, should the Examiner desire to maintain a double patenting rejection it is respectfully requested that applicants be given sufficient information so as to respond thereto, in a subsequent, non-final

Office Action.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/Harry B. Shubin/

---

Harry B. Shubin, Reg. No. 32,004  
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: MERCK-3100

Date: December 8, 2008